

Appl. No. : 09/636,278  
Filed : August 10, 2000

### REMARKS

Claims 43-64 are pending in the present application. By way of the present amendment, Applicant has amended the specification to reflect the current state of referenced patent applications. Furthermore, Applicant has amended the specification to properly identify trademarks. Applicant notes that the Examiner requested proper identification of the mark nitinol. However, there is no registration for the exclusive use of the word mark apart from stylized representations. Accordingly the word "nitinol" is a generic term and is currently used properly throughout the specification.

Claim 55 has been amended to more clearly define over the cited references. Claims 43-64 remain pending for consideration in view of the following comments.

### Claim rejections – 35 U.S.C. § 103

#### Claims 43-48, 51-57, and 60-64

Claims 43-48, 51-57, and 60-64 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,329,942 to Gunther et al. ("Gunther") in view of U.S. Pat. No. 5,720,754 to Middleman et al. ("Middleman"). The references will be briefly described and then applied to the claims which will be grouped by independent claim.

#### Discussion of Gunther

Gunther teaches a method for filtering blood in a blood vessel including a catheter and a positioning assembly having a filter distally attached thereto. The positioning assembly with attached filter is guided through the catheter. *See* Abstract. After inserting the catheter to a desired location, the filter basket is advanced through the catheter, and upon exiting the distal end thereof, it changes from a collapsed to an expanded state. Col. 6, lines 44-46. Once the filter basket is deployed to its expanded state, sliding lock assembly can be used to maintain the filter basket in that state. *Id.* at lines 46-49. Gunther further teaches that "[w]hen it is desired to collapse filter basket 11 such as for insertion into or removal from the blood vessel, sliding lock assembly 23 is pulled axially over central wire 15 toward coil segment 16 thus unlocking expander assembly 19. *Expander assembly 19 is then slid axially over central wire 15 toward coil segment 16 causing the proximal ends of wires 13 to advance axially over central wire 15 toward coil segment 16.* The axial movement of the proximal ends of wires 13 toward coil

segment 16 correspondingly causes filter basket 11 to collapse and to become longer and thinner." Col. 5, lines 37-47 (emphasis added). Thus, the filter basket is deployed by advancing the filter basket through the catheter until the filter basket exits the distal end of the catheter, and is subsequently retracted and later deployed by sliding expander assembly 19 over central wire 15.

Once the filter assembly is in place, a connection tube is provided to cover the portion of positioning assembly which extends beyond catheter and fitting in order to maintain the sterility of positioning assembly. Col. 6, lines 8-11.

#### Discussion of Middleman

Middleman discloses a device for surgical manipulation of matter within a living body. *See* Abstract. One embodiment of the device includes a remote actuator means to project and/or retract, and optionally, to rotate the barrier member relative to the distal deployment opening. Col. 25, line 67 et seq. Longitudinal axial movement of the activator means relative to the housing causes the barrier member to be extended from, or retracted into, the housing via the deployment opening. Col. 26, lines 60-63. Rotational movement of the activator means relative to the housing causes the barrier member to be rotated; however, if rotational movement is not desirable, a means to prevent rotation can be employed. *Id.*, at 63-67.

The barrier member of Middleman includes an elastically deformable loop and a barrier membrane. Col. 27, lines 62-63. The barrier membrane can be used as a surgical drape, or when more material is provided, can be used as a pouch to collect tissue. Col. 28, lines 4-10.

In use, the expanded barrier member is suspended internally at or near the surgical site. The barrier can be manipulated to underlie the surgical site, so that fluids or other materials which are released at the surgical site flow gently downhill into the expandable barrier. Col. 29, lines 11-16.

#### Claims 43-48, 51-54

There is no motivation to combine the optional rotatable aspect of Middleman with the blood filtering device of Gunther. Gunther relies only on axial movement to deploy a filter. The entire apparatus is pushed distally through a catheter until the filter basket exits the distal end of the catheter and is allowed to expand. Middleman offers optional rotation of the barrier

membrane to position the barrier to catch and retrieve fluid or other materials from a surgical site. There is no mention or suggestion of rotating, or allowing rotation of the filter basket taught by Gunther.

In fact, once the filter basket is in place, the filter basket cannot be rotated because Gunther teaches that a connection tube is provided to cover the portion of positioning assembly which extends beyond catheter and fitting in order to maintain the sterility of positioning assembly. *Id.* at lines 8-11. Thus, the positioning assembly is concealed and cannot be further manipulated, such as for rotating. Therefore, it would not have been obvious to substitute the positioning assembly of Gunther with the actuator of Middleman. Even if Gunther were rotatable as taught by Middleman, a filter that is rotatable once it is deployed does not make the claimed invention obvious.

In contrast, Claim 43 recites, *inter alia*, “the elongate member being longitudinally and rotationally moveable between a first position wherein the expandable member is in a collapsed configuration, and a second position wherein the expandable member is in an expanded configuration, and where in the elongate member moves longitudinally and rotationally as the expandable member moves from its collapsed configuration to its expanded configuration.” There is no teaching or suggestion in the cited references, either alone or in combination, for longitudinally displacing and rotating the elongate member as the expandable device goes from a first collapsed position to a second fully deployed position. At least these features are not taught or disclosed by Gunther or Middleman, either alone or in combination. In addition, the claims that depend from Claim 43 each recite a unique combination of features not taught or suggested by the references.

For example, Claim 45 recites, *inter alia*, “where the elongate member rotates to position the expandable member in its locked, expanded configuration.” Additionally, Claim 45 recites, *inter alia*, “wherein the elongate member rotates approximately 90 degrees to position the expandable member in its locked, expanded configuration.” These features are not taught or suggested by the cited references. Claims 44-48 and 51-54 each define over the prior art references and Applicant submits that these claims are in condition for allowance.

Appl. No. : 09/636,278  
Filed : August 10, 2000

Claims 55-57, and 60-64

As discussed above, Gunther teaches an apparatus that is insertable through a catheter, and when the apparatus is advanced sufficiently for the filter to be exposed beyond the distal end of the catheter, the filter resumes its natural, expanded shape. Likewise, Middleman teaches a barrier member that is pushed distally out of the axial bore so that it can resume its expanded configuration. These teachings do not make Claim 55 and its dependent claims obvious.

Specifically, amended Claim 55 recites *inter alia*, "the elongate member being longitudinally moveable between a first position wherein the expandable member is in a collapsed configuration, and a second position wherein the expandable member is in an expanded configuration, wherein the elongate member is pulled proximally from the first position to the second position with respect to the tubular member to expand the expandable member." At least these features are not taught or disclosed by Gunther or Middleman, either alone or in combination. To the contrary, both references require a distal advancing of their respective actuators followed by self-expanding of the respective expandable devices once the expandable devices extend beyond the distal end of the respective catheter or sheath.

In addition, the claims that depend from Claim 55 each recite a unique combination of features not taught or disclosed by the cited references. For instance, Claim 57 recites, *inter alia*, "wherein the handle has a cross-sectional profile in one transverse dimension that equals a diameter of the outer surface of said tubular body."

Applicant respectfully submits that Claims 55-57, and 60-64 each define over the prior art of record and are in condition for allowance, and Applicant respectfully requests the same.

Claims 49, 50, 58, and 59

As discussed above, there is no suggestion of modifying Gunther with a rotatable actuator as in Middleman. As such, Claim 49, 50, 58, and 59 are not made obvious in view of the prior art. Furthermore, there is no teaching or suggestion of combining Mische with the devices of Gunther or Middleman. However, even if the device of Gunther were modified as suggested by Mische, such a device would not make the claimed invention obvious in view of the above arguments. Claims 49 and 50 depend from independent Claim 43 and are patentable for at least the reasons that claim is patentable. Likewise, claims 58 and 59 depend from Claim 55 and are patentable for at least the reasons that claim is patentable. Moreover, Claims 49, 50, 58, and 59

**Appl. No.** : **09/636,278**  
**Filed** : **August 10, 2000**

each recite a unique combination of features that is not obvious in view of the prior art, and are thus in condition for allowance.

Appl. No. : 09/636,278  
Filed : August 10, 2000

### CONCLUSION

The specification has been amended to properly identify related applications and also to properly identify trademarks. No new matter has been introduced by way of the amendments to the specification. Claim 55 has been amended to more clearly define over the prior art of record. Claims 43-64 remain pending for consideration.

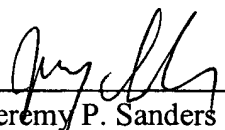
Applicant has endeavored to respond to each issue presented by the Examiner; however, if there remain any unresolved issues the Examiner is invited to initiate a telephone conference with Applicant's representative at the telephone number shown below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 30 June 2003

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